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TC 1700

Applicant: William H. Velander, et al.  
Title: EXPRESSION OF ACTIVE HUMAN  
FACTOR IX IN MAMMARY TISSUE OF  
TRANSGENIC ANIMALS  
Appl. No.: 10/062,447  
Filing Date: 02/05/2002  
Examiner: Unassigned  
Art Unit: 1632

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the foreign search report.

RELEVANCE OF EACH DOCUMENT

Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding European application. A copy of the European Search Report is attached setting forth the portion of each document considered relevant by the examiner. An English-language translation of the foreign-language document is not readily available. The absence of a translation or an English-language counterpart document does not relieve the PTO from its duty to consider any submitted document (37 CFR §1.98 and MPEP§609).

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date

January 9, 2003

FOLEY & LARDNER

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TC 1700

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Date Submitted: January 9, 2003

(use as many sheets as necessary)

Sheet

of

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## Complete if Known

Application Number	10/062,447
Filing Date	02/05/2002
First Named Inventor	William H. VELANDER et al
Group Art Unit	1632
Examiner Name	Unassigned
Attorney Docket Number	030523-0185

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	5,171,569		ANSON ET AL.	12/15/1992	
	A2	5,366,894		CLARK ET AL.	11/22/1994	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A3	UK	2 125 409	A	NATIONAL RESEARCH DEVELOPMENT CORPORATION	03/07/1984		
	A4	EP	0 451 823	A2	CONSORTIUM FÜR ELEKTROCHEMISCHE INDUSTRIE GMBH	10/16/1991		
	A5	WO	95/30000	A1	BIOTECHNOLOGY AND BIOLOGICAL SCIENCES RESEARCH COUNCIL	11/09/1995		

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A6	YULL ET AL., "Fixing human factor IX (fIX): Correction of a cryptic RNA splice enables the production of biologically active fIX in the mammary gland of transgenic mice," <i>Proc. Natl. Acad. Sci.</i> (1995), Vol. 92, pp. 10899-10903, XP-002207339, ISSN: 0027-8424.	
	A7	MORCOL ET AL., "The Porcine Mammary Gland as a Bioreactor for Complex Proteins," <i>Annals of the New York Academy of Sciences</i> (1994), Vol. 721, pp. 218-233, XP-001094224, ISBN: 0-89766-822-7.	
	A8	WRIGHT ET AL., "High Level Expression of Active Human Alpha-1-Antitrypsin in the Milk of Transgenic Sheep," <i>Bio/Technology</i> (1991), Vol. 9, pp. 830-834, XP00202118, ISSN: 0733-222X.	
	A9	CLARK ET AL., "Expression of Human Anti-Hemophilic Factor IX in the Milk of Transgenic Sheep," <i>Bio/Technology</i> (1989), vol. 7, No. 5, pp. 487-492, XP000026727, ISSN: 0733-222X.	
	A10	WALL, "Transgenic Livestock: Progress and Prospects for the Future," <i>Theriogenology</i> (1996), Vol. 45, pp. 57-68, XP002917341, ISSN: 0093-691X.	
	A11	MASSOUD ET AL., "The deleterious effects of human erythropoietin gene driven by the rabbit whey acidic protein gene promoter in transgenic rabbits," <i>Reprod. Nutr. Dev.</i> (1996), Vol. 36, pp. 555-563, XP001084633.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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